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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,249	01/26/2004	Naoto Tonouchi	247264US0CONT	8012
22850	7590	07/25/2006		
C. IRVIN MCCLELLAND OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,249

Applicant(s)

TONOUCHI ET AL.

Examiner

Malgorzata A. Walicka

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 35-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Amendment and Request for Reconsideration filed on June 22, 2006 is acknowledged. Claims 1-49 are pending; the elected claims 1-34 are under examination.

DETAILED ACTION

1. Priority

Acknowledgment is made of Applicant's claim for priority based on Japanese applications 2001-226568 filed 07/26/2001 and 2001-310547 filed 10/05/2001. However priority documents are not translated and do not contain any sequence listing. Thus the priority of the instant claims to the Japanese applications have not been granted.

The instant application is a continuation of the PCT/JP01/07635, filed 07/26/2002. This application has been published on Feb. 06, 2003 as document WO03/10307. However, the document is published in Japanese and Applicants have not provided a translation. For that reason priority of the instant claims to the PCT application is not granted. In results, the instant claims have priority to the filing date of this utility application, which is 01/26/2004.

2. Objections

The specification was objected to in the Office Action of March 24, 2006 (previous action). The objection is withdrawn because the amendment to the specification has been filed.

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Objections to claims 4 and 5 as reciting the term "base sequence" to mean "nucleotide sequence" is withdrawn, because the claims have been amended.

Objections to claims 11-14 for the phrase «in a state where the DNA is able to express» is withdrawn, because the claims have been amended.

3. Rejections

3.1. 35 USC, section 101

Rejection of claims 1, 2, 3 and 4 made in the previous action is withdrawn because the claims have been amended.

3.2. 35 USC, section 112, second paragraph

Rejections of claims 1-2, 3-4, 11-14, 19-22 made in the previous action are withdrawn because the claims have been amended.

Rejections caused by amendment

Claims 5-6 and dependent claims 9-10, 13-14, 17-18, 21-22, 25-26, 29-30, 33-34 are rejected as being confusing.

Claim 5 and 6 are directed to DNA of claim 3 and 4 wherein said DNA hybridizes to a DNA sequence complementary to nucleotides 486-14956 of SEQ ID NO:14 or nucleotides 311-1279 of SEQ ID NO: 16 under stringent hybridization conditions. It is not clear what stringent hybridization conditions Applicants mean in claims 5 and 6. If these are new stringent conditions, the claims seek to broaden the scope of claim 3 and

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4 from which they depend. If these are the same hybridization conditions as those in the base claims 3 and 4 the phrase "under stringent conditions" is redundant. It is assumed for examination purposes that the conditions of claims 5 and 6 are the same as those of claims 3-4.

3.3. 35 USC, section 112, first paragraph

3.3.1. Lack of written description

Claim 1 and 2, and respective claims 3-4 directed to encoding DNA, were rejected for lack of written of polypeptides that are obtained from SEQ ID NO:15 and 17 by any substitution, deletion, insertion and/or addition of one or plurality of amino acids and retain the required enzymatic activity. The current amendment narrowed down the plurality of changes to up to 10 changes which is equivalent to sequences having 97% identity to SEQ ID NO: 15 and 17. The rejection is therefore withdrawn.

4.3.2. Scope of enablement

Rejection withdrawals

Claims 1 – 2 were rejected because the specification, while being enabling for SEQ ID NO: 15 and 17 identifying two peptide forming enzymes originating from *Pseudomonas putida*, does not reasonably provide enablement for any peptide forming enzyme obtained by modifications of SEQ ID NO: 15 and 17. This rejection is now withdrawn, because the amendment narrows the changes to 10 per molecule of about 300 amino acids, which is about 3%, i.e. the claims are actually directed to

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polypeptides having 97% identity to SEQ ID NO: 15 or 17. The amount of experimentation necessary for selecting mutants having this level of identity is currently considered as not undue.

Rejection caused by amendment

Claims 3-4 and dependent claims 5-33 and 34 are rejected for scope of enablement because of lack of hybridization conditions stated in the claims or because the hybridization conditions comprising washing at 60 °C and a salt concentration equivalent to 1 x SSC and 0.1% SDS are considered by those having skills in the art medium stringency conditions that allow for hybridizing DNA having 80%-90% of identity. The number of DNA molecules selected under any stringent conditions or moderately stringent conditions is enormously large, thus, one skilled in the art is forced to express this enormously large number of selected DNA molecules and screen the resulting protein molecules for their activity of the peptide forming enzyme, and further select those having the desired activity. In result, the experimentation left to those skilled in the art does not have a high probability of success and is undue.

3.3. 35 USC section 102

Rejection withdrawal

Rejection of claim 1, made in the previous action under 35 U.S.C. 102(b), as being anticipated by *Pseudomonas putida* prolyl aminopeptidase having accession number Q88D01 and disclosed in Nelson K.E. et al., "Complete genome sequence and

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comparative analysis of the metabolically versatile *Pseudomonas putida* KT2440", Environ. Microbiol. 2002, 4, 799-808, is withdrawn, because the claim has been amended.

Rejection of claims 1 and 2, made in the previous action under 35 U.S.C. 102(b), as being anticipated by prolyl aminopeptidase from *Pseudomonas aeruginosa*, having accession number B83010, and disclosed in Stover R. et al., "Complete genome sequence of *Pseudomonas aeruginosa* PA01, an opportunistic pathogen, Nature, 2000, 406, 959-964, is withdrawn because the claims have been amended.

4. Conclusion

Claims 1-34 are rejected, however the claims contain allowable subject matter. The following is the examiner reasons for indicating allowable subject matter. Applicants are the first to disclose two enzymes from *Pseudomonas putida* of SEQ ID Nos: 15 and 17, and their encoding DNA of SEQ ID NOs:14 and 16. No prior art teaches of fairly suggest the enzymes. The enzymes have the application in synthesis of dipeptides.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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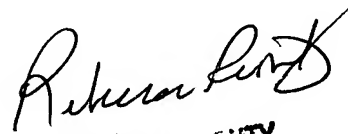
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner


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